

## **REMARKS**

### **1. Claims**

Claims 148 - 151 and 182 - 225 are pending. Claims 1 - 147 and 152 - 181 are Canceled. Claims 182 - 225 are New.

The claims have been renumbered and should be in the proper order. The Examiner is thanked for the considerable work involved in determining the proper number for each claim and renumbering the claims accordingly.

### **2. Information Disclosure Statement**

Examiner stated that references listed in the application do not satisfy the requirement for Disclosure. Applicants submitted an IDS with the filing of the above application and these references were considered by the Examiner on June 24, 2005.

### **3. Terminal Disclaimer**

Examiner pointed out that an incorrect patent number was used in the Terminal Disclaimer. A Terminal Disclaimer citing the correct Patent Number - 6,258,870 -- has been filed in conjunction with this response.

### **4. Specification - Numbering of Claims**

Examiner pointed out that the numbering of the claims was improper and did not follow the USPTO procedures for numbering of New Claims. The claim numbers have been corrected to follow the USPTO procedures and should be in proper order. Examiner is thanked for his assistance in correcting this error.

### **5. 35 U.S.C. § 112 ¶ 1 Rejections**

#### **Claims 168 - 181**

Examiner rejected Claims 168 - 181 under 35 U.S.C. § 112 ¶ 1 because the specification, while being enabling for the method set forth in claim 166, does not reasonably provide enablement for the method of claim 166 wherein step b is eliminated and step c is modified as set forth in claim 166.

Applicant has canceled Claims 168 - 181. Applicant respectfully asks for the withdrawal of this 35 USC §112 ¶ 1 rejection as being moot.

Claims 129, 134, 135, 137, 138 and 160

Examiner rejected Claims 129, 134, 135, 137, 138 and 160 under 35 U.S.C. § 112 ¶ 2, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from a canceled claim and should be rewritten to depend from claim 166.

Applicant has canceled Claims 129, 134, 135, 137, 138 and 160. Applicant respectfully asks for the withdrawal of this 35 USC §112 ¶ 2 rejection as being moot.

**6. 35 U.S.C. § 102/103 Rejections**

Claims 166, 129-135, 137, 138, 167, 152-154, 156-162 and 164-165

Examiner rejected Claims 166, 129-135, 137, 138, 167, 152-154, 156-162 and 164-165 under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al. (5,700,848 or 5,705,270 or 5,846,530).

Additionally, Examiner rejected Claims 166, 129-135, 137, 138, 167, 152-154, 156-162 and 164-165 under 35 U.S.C. 102(e) as being anticipated by Soon-Shiong et al. (5,545,423 or 5,759,578 or 5,788,988 or 5,879,709).

Applicant has canceled Claims 166, 129-135, 137, 138, 167, 152-154, 156-162 and 164-165. Applicant respectfully asks for the withdrawal of this 35 USC §102(e) rejection as being moot.

**7. Double Patenting**

Examiner rejected Claims 129-135, 137, 138 and 166 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-58 of U.S. Patent No. 6,258,870.

Applicant has filed a Terminal Disclaimer citing Patent Number - 6,258,870 -- in conjunction with this response. Applicant respectfully asks for the withdrawal of this Double Patenting rejection as being moot.

## **8. Previously Presented and New Claims**

Previously presented Claims 148 - 151 and New Claims 182 - 225 are pending. In order to assist the examination of the claims by the Examiner, the above claims can be separated into 3 sets of similar claims except for the biological material encapsulated in the microspheres.

“At least one cell” is encapsulated in a microcapsule in Claims 148 - 151 and 182 - 193. “At least one aggregation of cells” is encapsulated in a microcapsule in Claims 194 - 209. “At least one islet” is encapsulated in a microcapsule in Claims 210 - 225.

### Claims 148 - 151 and 182 - 193

Examiner stated that Claim 148 is considered to be supported by the evidence for reduction to practice before the effective filing date of Soon-Shiong et al. Applicant believes Claims 148 - 151 and 182 - 225 are allowable and respectfully asks the Examiner to allow these claims.

### Claims 194 - 209

Claims 194 - 209 contain the limitation of “at least one aggregation of cells” is encapsulated in a microcapsule. Support for this limitation can be found in the specification in Figures 2A, and paragraph [0073] in the specification.

*[0073] Examples of cells that [which] can be encapsulated are primary cultures as well as established cell lines, including transformed cells. These include but are not limited to pancreatic islet cells, human foreskin fibroblasts, Chinese hamster ovary cells, beta cell insulomas, lymphoblastic leukemia cells, mouse 3T3 fibroblasts, dopamine secreting ventral mesencephalon cells, neuroblastoid cells, adrenal medulla cells, and T-cells. ...*

A beta cell insuloma is a “benign tumor of the islets of Langerhans”; which meets the definition of an aggregation of cells.

Claims 210 - 225

Claims 210 - 225 contain the limitation of “at least one islet” encapsulated in a microcapsule. Support for this limitation can be found in the specification in Figures 2A & 2B, and paragraph [0066] in the specification.

*[0066] A schematic representation of this process is shown in FIG. 2A. The amount, thickness or size and rigidity of the gel formed will depend on the size and intensity of the beam, time of exposure, initiator, macromer molecular weight, and macromer concentration (see below). Alginate/PLL microspheres containing islets coated by this technique are shown in FIG. 2B.*

Support for a Date of Invention before any of the cited Soon-Shiong et al. applications can be found in the previously filed Declaration by Jeffrey Hubbell. Exhibit A is a letter describing alginate microcapsules containing islets being encapsulated with PEG to form macrocapsules. Although, it is not directly stated the alginate microcapsules contain islets, it can be deduced by the address of the recipient [Diabetes Research and Management Center] and the discussion of implanting the macrocapsules in dogs to extend the effective period beyond 4-6 months.

## CONCLUSION

The claims have been amended to claim more precisely the disclosed invention. No new matter has been added by the amendments to the claims.

This Response to a Non-Final Rejection is filed within 3 months of the mailing of the Office Action and no fees are believed due; however, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to credit card information on record.

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Date: August 8, 2006

/KOH/

Kirk Hahn, Ph.D.  
Agent of Record  
Registration Number: 51,763  
Customer Number: 036,647  
(949)-727-1942 ext. 217